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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/597,835	08/09/2006	Serge Louis Boulet	X-16288	6937
25885	7590	09/05/2007		
ELI LILLY & COMPANY PATENT DIVISION P.O. BOX 6288 INDIANAPOLIS, IN 46206-6288			EXAMINER LOEWE, SUN JAE Y	
			ART UNIT 1626	PAPER NUMBER
			NOTIFICATION DATE 09/05/2007	DELIVERY MODE ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patents@lilly.com

<b>Office Action Summary</b>	<b>Application No.</b> 10/597,835	<b>Applicant(s)</b> BOULET ET AL.	
	<b>Examiner</b> Sun Jae Y. Loewe	<b>Art Unit</b> 1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 20 August 2007.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1,6-8,15,21 and 33 is/are pending in the application.
- 4a) Of the above claim(s) 7 and 21 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,6,8,15 and 33 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>8/9/2006</u> . | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Election/Restrictions***

1. Applicant's election without traverse of compound of example 30, (S)-[3-(2,4-Dichloro-phenoxy)-hexyl]-methanamine, in the reply filed on August 20, 2007 is acknowledged. In view of Applicant's response and amendment to the claims, the restriction requirement between Groups I-X dated July 20, 2007 is withdrawn.
2. Claims 7 and 21 withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected subject matter: the claims reading on the elected species are 1, 6, 8, 15 and 33.
3. MPEP § 803.02 provides guidelines for election of species in Markush-type claims. These guidelines were followed for the search and examination detailed herein.

The elected species was not found to be allowable. Therefore, the Markush-type claims were rejected and the subject matter drawn to nonelected species held withdrawn from further consideration. The provisional election of species was given effect and the search was limited to the elected species. Claims 1, 6, 8, 15 and 33 were further examined, pursuant to MPEP § 803.02, to the extent necessary to determine patentability.

### ***Information Disclosure Statement***

4. The information disclosure statement (IDS) submitted on August 9, 2006 was in compliance with the provisions of 37 CFR 1.97 and 37 CFR 1.98. Accordingly, the information disclosure statement was considered. A signed copy of form 1449 is submitted herewith.

***Claim Objections***

5. Claims 1, 6, 8, 15 and 33 objected to for containing non-elected subject matter.
6. Claims 6 and 7 objected to because of the following informality: the claims do not end with a period. Appropriate correction is required pursuant MPEP § 608.01(m).

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

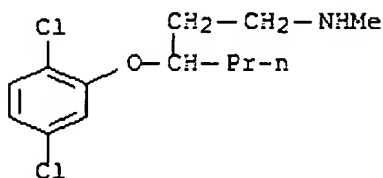
The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
  2. Ascertaining the differences between the prior art and the claims at issue.
  3. Resolving the level of ordinary skill in the pertinent art.
  4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
7. Claims 1, 6, 8, 15 and 33 rejected under 35 U.S.C. 103(a) as being obvious over Cheshire et al. (WO 01/62714). See, for example, compound on page 6 line 14.

*Determination of the scope and contents of the prior art.*

The references teaches the following compound which is an inhibitor of nitric oxide synthases.

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Ascertaining the differences between the prior art and the claims at issue.

The difference in the prior art compound to the instantly elected species is the following: the chloro substituents are on the 2 and 4 positions of the phenyl ring for the instantly elected compound; the equivalent substituents are on the 2 and 5 positions for the prior art compound. The instant election is a positional isomer of the prior art compound.

Resolving the level of ordinary skill in the pertinent art – Prima Facie Case of Obviousness.

Position isomers are generally of sufficiently close structural similarity that there is a presumed expectation that such compound possess similar properties. MPEP §2144.09, *Ex parte Henkel* 130 USPQ 474, (1-phenyl-3-methyl-4-hydroxypyrazole obvious over reference teaching 3-phenyl-5-methyl-4-hydroxypyrazole). *Ex parte Weston*, 121 USPQ 429.

One of ordinary skill would be motivated to make the modification required to arrive at the instant invention with reasonable expectation of obtaining a compound that is an inhibitor of nitric oxide synthase. The motivation would be to make alternate compounds that are inhibitors of nitric oxide synthase.

Thus, the instant claims are *prima facie* obvious over the teachings of the prior art.

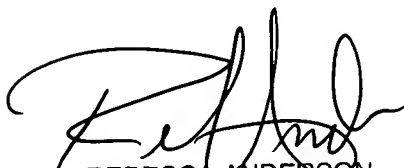
**Conclusion**

8. No claims allowed.
9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sun Jae Y. Loewe whose telephone number is (571) 272-9074. The examiner can normally be reached on M-F 7:30-5:00 Est.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph McKane can be reached on (571)272-0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Sun Jae Y. Loewe, Ph.D.  
Art Unit 1626



REBECCA ANDERSON  
PRIMARY EXAMINER